Kiadis Pharma and The Leukemia & Lymphoma Society strengthen partnership around the development of ATIR101™ in ALL and AML patients

~ LLS makes second equity investment in Kiadis Pharma for the Phase II development ~

Amsterdam, The Netherlands, July 11, 2016 – Kiadis Pharma N.V. (“Kiadis Pharma” or the “Company”) (Euronext Amsterdam and Brussels: KDS), a clinical stage biopharmaceutical company developing innovative T-cell immunotherapy treatments for blood cancers and inherited blood disorders, today announces that its partnership with The Leukemia & Lymphoma Society (LLS), the world’s largest voluntary health agency focused on blood cancers, has been strengthened with a second equity investment by LLS into the development of Kiadis Pharma’s lead product ATIR101™.

LLS initially invested approximately US$1 million in February 2016 through an equity investment via its Therapy Acceleration Program (TAP), a strategic initiative to partner directly with biotechnology companies to help accelerate the development of promising therapies. This second investment will now also be used to finance Kiadis Pharma’s second ongoing Phase II trial in leukemia patients which the Company then intends to continue into a randomized controlled Phase III pivotal study on track to start later this year. The ongoing Phase II trial is investigating the repeated dosing of ATIR101™ as an adjunctive treatment to a T-cell depleted haploidentical hematopoietic stem cell transplantation (HSCT) (donor cells from a half-matched related donor) in adult patients with acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL). The trial (CR-AIR-008; NCT02500550 / EudraCT 2015-002821-20) is conducted under an IND of the United States Food and Drug Administration and is set up to enroll patients in the United States as well as other countries, including Canada, Belgium, Germany and the United Kingdom.

The second funding by LLS has taken place through an equity investment of approximately US$750,000 and a total of 67,020 shares will be issued to LLS.

Manfred Rüdiger, PhD, Chief Executive Officer of Kiadis Pharma, commented: “We are delighted that LLS has made another significant contribution to the development of our lead product ATIR101™ and invested further in Kiadis Pharma. This is again a strong sign of confidence in what we do and our goal remains to be to bring this important product to patients as quickly as possible.”

Louis J. DeGennaro, Ph.D., LLS’s President and CEO, added: “Kiadis Pharma’s ATIR101™ shows great promise in fighting life-threatening infections and graft versus host disease following stem cell transplantations. LLS is very pleased to be increasing its level of support for this program which we hope will improve outcomes for patients with blood cancers.”
About ATIR101™
For patients suffering from blood cancers, an allogeneic hematopoietic stem cell transplantation (HSCT) is generally regarded as the most effective curative approach. During an HSCT treatment, the bone marrow, harboring the diseased cancer cells, is completely destroyed and subsequently replaced by stem cells in the graft from a healthy donor. After an HSCT treatment it usually takes the patient at least six to twelve months to recover to near-normal blood cell levels and immune cell functions. During this period, the patient is highly vulnerable to infections caused by bacteria, viruses and fungi but also to disease relapse.

ATIR101™ (Allodepleted T-cell ImmuInotheRapeutics) provides for a safe donor lymphocyte infusion (DLI) from a partially matched (haploidentical) family member without the risk of causing severe Graft-versus-Host-Disease (GVHD). The T-cells in ATIR101™ will help fight infections and remaining tumor cells and thereby bridge the time until the immune system has fully re-grown from stem cells in the transplanted graft.

In ATIR101™, T-cells that would cause GVHD are eliminated from the donor lymphocytes using Kiadis Pharma’s photodepletion technology, minimizing the risk of GVHD and eliminating the need for prophylactic immune-suppression. At the same time, ATIR101™ contains potential cancer killing T-cells from the donor that could eliminate residual cancer cells and help prevent relapse of the disease, known as the Graft-versus-Leukemia (GVL) effect.

Therefore, ATIR101™, administered as an adjunctive immuno-therapeutic on top of HSCT, provides the patient with functional, mature immune cells from a partially matched family donor that can fight infections and tumor cells but that do not cause GVHD. ATIR101™ thus has the potential to make curative HSCT a viable option to many more patients.

The Company estimates that approximately 35% of patients who are eligible and in urgent need of HSCT will not find a matching donor in time. A partially matched (haploidentical) family donor, however, will be available to over 95% of patients.

ATIR101™, consisting of donor T-cells that fight infections and residual tumor cells while not eliciting severe GVHD, is designed to result in low relapse rates and low rates of death due to infections, in the absence of severe acute GVHD.

About Kiadis Pharma
Kiadis Pharma is focused on cell-based immunotherapy products for the treatment of blood cancers and inherited blood disorders. The Company’s products have the potential to address the risks and limitations connected with allogeneic hematopoietic stem cell transplantation (HSCT), namely Graft-versus-Host-Disease (GVHD), cancer relapse, opportunistic infections and limited matched donor availability. The Company believes that HSCT could become a first-choice treatment for blood cancers, inherited blood disorders and possibly autoimmune diseases and solid organ transplantations.

In April 2016, the Company reported positive Phase II results with its lead product ATIR101™ in patients with blood cancer. The data showed that ATIR101™ significantly reduced Transplant Related Mortality and significantly improved Overall Survival. In addition, ATIR101™ did not elicit grade III-IV GVHD in any patient. ATIR101™ has been granted Orphan Drug Designations both in the US and Europe. The Company’s second product candidate, ATIR201™, addresses inherited blood disorders with an initial focus on thalassemia, a disease which results in destruction of red blood cells in patients. ATIR201™ is expected to enter
Phase I/II clinical development in the second half of 2016.

Kiadis Pharma, based in Amsterdam, The Netherlands, was granted an Advanced Therapy Medicinal Product (ATMP) certificate for manufacturing quality and non-clinical data by the European Medicines Agency (EMA). The Company’s shares are listed on Euronext Amsterdam and Euronext Brussels. For more information visit www.kiadis.com

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